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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,512	07/23/2003	Henry Li	016556-003110US	1972

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EXAMINER	
SHIN, DANA H	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/626,512	LI ET AL.	
	Examiner	Art Unit	
	Dana Shin	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-30* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-11, drawn to a DNA expression cassette, comprising a double-stranded randomized DNA sequence, classified in class 536, subclass 24.5.

II. Claims 12-17, drawn to a library of DNA expression cassettes, wherein each DNA expression cassette produces a different dsRNA, classified in class 536, subclass 24.5.

III. Claims 18-22, drawn to a method for producing a library of DNA expression cassettes for expressing dsRNA, classified in class 435, subclass 4.

IV. Claims 23-30, drawn to a method of correlating expression of a transcription sequence for an siRNA with a phenotypic change, comprising introducing a library of siRNAs to an eukaryotic cell population, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related product. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the DNA expression cassette of group I is materially

different from the library of DNA expression cassettes of group II because the transcription of the expression cassette of group I produces a dsRNA while that of the library of group II produces multiple different dsRNAs. Moreover, groups I and II do not overlap in scope because the expression cassette of group I cannot be used for the purpose of screening a genome as the library of group II can. Due to the material and functional differences, groups I and II are not obvious variants of each other. Because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner, and restriction for examination purposes as indicated is proper therefore.

The invention of group I is unrelated to inventions of groups III-IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the DNA expression cassette of group I is not disclosed to be used together with the methods of groups III and IV because the methods of groups III and IV comprise a library of expression cassettes or siRNAs, but not a single expression cassette. As explained above for distinctness between groups I and II, an expression cassette and a library of expression cassettes have different designs and utility. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are divergent and non-coextensive for the reasons given above and the

inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner.

Inventions II and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the library of DNA expression cassettes of group II is produced by the method of group III. The library of DNA expression cassettes for expressing dsRNA can be made by materially different process which does not comprise synthesizing a plurality of single-stranded DNA sequences. For example, one of skill in the art could produce a library of DNA expression cassettes for expressing dsRNA comprising method steps of digesting the gene of interest by recombinant human Dicer or bacterial RNase III or DNase I in the presence of Mn^{2+} to generate fragments with blunt ends to produce 16-25 bp siRNAs, which are subsequently converted into corresponding DNA fragments through ligation of adapters and reverse transcription-PCR (RT-PCR). The resulting PCR products can then be cloned into an siRNA expression vector between two promoters and are operably linked to promoters. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not

necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the library of DNA expression cassettes of group II is used in the method of group IV. However, the product of group II can be also used in a materially different process such as conditional transient knock-out mouse model *in vivo*, wherein the activity of the double-stranded DNA is induced upon tetracycline injection. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner.

Inventions III and IV are directed to related process. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See

MPEP § 806.05(j). In the instant case, both methods of groups II and III comprise a library of DNA expression cassettes. However, these methods are directed to distinct processes because the method of group II is directed to producing the product of group I while that of group III is directed to using the product of group III. Thus, the method steps, processes, and ingredients for these inventions do not overlap in scope, are not obvious variants, and do not have same material design. because these inventions are divergent and non-coextensive for the reasons given above and the inventions require different keyword searches and art against one would not necessarily apply against another (see MPEP § 808.02), to search them together represent a search burden on the examiner, and restriction for examination purpose as indicated is proper therefore.

Election of Species

Claim 23 is generic to the following disclosed patentably distinct species: a fluorescent protein, a cell surface protein, and a drug resistance gene of claim 29. The species are independent or distinct because each detectable marker protein/gene above has a unique structural and chemical composition that is not shared by another.

Claim 23 is generic to the following disclosed patentably distinct species: inhibition of cell division, viral gene expression, excretion of an extracellular protein, expression of a cell surface marker, a genetic suppressor, a signal transduction pathway, or cell death of claim 30. The species are independent or distinct because each phenotypic difference of the detecting step above is directed to a distinct cellular process or expression marker. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species

that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Notice of Potential Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim

will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana Shin whose telephone number is 571-272-8008. The examiner can normally be reached on Monday through Friday, from 8am-4:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Dana Shin
Examiner
Art Unit 1635

D. Shin
5-1-2006

JAMES SCHULTZ, PH.D.
PRIMARY EXAMINER